

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (withdrawn) A method to determine the degree of serum cholesterol elevation which will occur in a patient during treatment with an immunosuppressant medication comprising:
 - a) determining for the two copies of the IL-1 β gene present in the patient the identity of the nucleotide pair at the polymorphic site -511 C→T (at position 1423 of sequence X04500) of the IL-1 β gene; and
 - b) assigning the patient to a high cholesterol elevation group if both pairs are AT, assigning the patient to an intermediate cholesterol elevation group if one pair is AT and one pair is GC and assigning the patient to a low cholesterol elevation group if both pairs are GC.
2. (withdrawn) A method to treat a patient with an immunosuppressive medication comprising:
 - a) determining for the two copies of the IL-1 β gene present in the patient the identity of the nucleotide pair at the polymorphic site -511 C→T (position 1423 of sequence X04500) of the IL-1 β gene; and
 - b) treating the patient with the immunosuppression medication if both pairs are GC and using alternative treatment if one pair is AT and one pair is GC or if both pairs are AT.
3. (withdrawn) The method of claim 2, wherein the immunosuppressive medication is selected from the list in Table 2.
4. (withdrawn) The method of claim 3, wherein the immunosuppressive medication is everolimus.
5. (withdrawn) The method of claim 2, wherein the alternative treatment comprises the addition of a cholesterol-lowering medication chosen from those listed in Table 1.
6. (currently amended) A method of determining predisposition to determine the degree of serum cholesterol elevation which that will occur in a human patient during treatment with an immunosuppressant medication everolimus, said method comprising:a) determining assaying a blood sample obtained from the patient to determine for the two copies of the IL-1 β gene present in the patient the identity of the nucleotide pair at the polymorphic site -31 T→C (position 1903 of SEQ ID No.11) of the human IL-1 β gene, which is position 1903 of SEQ ID NO:11, wherein the

presence of C at the polymorphic in at least one copy of the IL-1 β gene indicates that the patient is predisposed to serum cholesterol elevation in response to treatment with everolimus; and

b) assigning the patient to a high cholesterol elevation group if both pairs are CG, assigning the patient to an intermediate cholesterol elevation group if one pair is AT and one pair is GC and assigning the patient to a low cholesterol elevation group if both pairs are AT, wherein said immunosuppressant medication is at least one of rapamycin, everolimus, mycophenolic acid, mycophenolate mofetil, azathioprine, cyclosporine, or tacrolimus.

7. (currently amended) A method to treat a human patient with an immunosuppressive medication everolimus comprising:

a) determining assaying a blood sample obtained from the patient to determine for the two copies of the IL-1 β gene present in the patient the identity of the nucleotide pair at the polymorphic site -31 T→C (position 1903 of SEQ ID No.11) of the human IL-1 β gene, which is position 1903 of SEQ ID NO:11; and

b) treating the patient with the immunosuppression medication everolimus if the patient has a T at the polymorphic site in the two copies of the IL-1 β gene both pairs are AT and using alternative treatment if the patient has a C at the polymorphic site -31 T→C in at least one copy of the IL-1 β gene one pair is AT and one pair is GC or if both pairs are CG, wherein said immunosuppressant medication is at least one of rapamycin, everolimus, mycophenolic acid, mycophenolate mofetil, azathioprine, cyclosporine, or tacrolimus.

8-9. (cancelled)

10. (currently amended) The method of claim 7 wherein the alternative treatment comprises the addition of a cholesterol-lowering medication chosen from a bile acid sesquesterant sequestrant, a fibrin acid derivative, an HMG-CoA reductase inhibitor, and nicotinic acid.

11. (withdrawn) A method to determine the degree of serum cholesterol elevation which will occur in a patient during treatment with an immunosuppressant medication comprising:

a) determining, for the two copies of the chromosome containing the IL-1 β gene, present in the patient, the haplotype with regard to the IL-1 β gene and,

b) assigning the patient to a high cholesterol elevation group if both said copies contain the "high cholesterol" haplotype and,

c) assigning the patient to an intermediate cholesterol elevation group if one said copy contains the "high cholesterol" haplotype and one contains the "low cholesterol" haplotype and,

d) assigning the patient to a low cholesterol elevation group if both said copies contain the "low cholesterol" haplotype.

12. (withdrawn) A method to treat a patient with an immunosuppressive medication comprising:

- a) determining, for the two chromosomes containing the IL-1 β gene present in the patient, the haplotype with regard to the IL-1 β gene,
- b) treating the patient with the immunosuppression medication if both said chromosomes contain the "low cholesterol" haplotype, and using alternative treatment if one said chromosome contains the "low cholesterol" haplotype and one contains the "high cholesterol" haplotype or both said chromosomes contain the "high cholesterol" haplotype.

13. (withdrawn) The method of claim 12, wherein the immunosuppressive medication is selected from the list in Table 2.

14. (withdrawn) The method of claim 13, wherein the immunosuppressive medication is everolimus.

15. (withdrawn) The method of claim 12 wherein the alternative treatment comprises the addition of a cholesterol-lowering medication chosen from those listed in Table 1.

16. (currently amended) The method of claim 6 wherein the ~~process of determining step of assaying is achieved by determining the nucleotide pair at polymorphic site -511 C→T of the IL-1 β gene, which is position 1423 of SEQ ID NO:11 or the haplotype comprises finding SNPs anywhere in a chromosome which are in linkage disequilibrium with the -511 polymorphism or the -31 polymorphism in the human IL-1 β gene and using the relationship of the said SNP or SNPs to determine the nature of the nucleotide pair or haplotype of interest.~~

17. (withdrawn) A kit for determining the nucleotide pair at the polymorphic site - 511 in the IL-1 β gene in a patient, comprising:

- a) a container containing at least one reagent specific for detecting the nature of the nucleotide pair at the polymorphic site -511 of the IL-1 β gene; and
- b) instructions for recommended treatment options based on the nature of the said nucleotide pair.

18. (withdrawn) A kit for determining the nucleotide pair at the polymorphic site -31 in the IL-1 β gene in a patient, comprising:

- a) a container containing at least one reagent specific for detecting the nature of the nucleotide pair at the polymorphic site -31 of the IL-1 β gene; and
- b) instructions for recommended treatment options based on the nature of the said nucleotide pair.

19. (withdrawn) A kit comprising the kit of claim 17 with instructions for determining the nature of the haplotype of the IL-1 β gene from the results of the above kits and instructions for recommended treatment options based on the nature of the indicated haplotype.